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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,115	02/08/2000	Jens Ponikau	07039-104002	2144
26191	7590	07/08/2004	EXAMINER	
FISH & RICHARDSON P.C. 3300 DAIN RAUSCHER PLAZA 60 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402			LAMM, MARINA	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/500,115

Applicant(s)

PONIKAU, JENS

Examiner

Marina Lamm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/4/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-120,122,123,127-129,135-137,143-145,194-243,366 and 367 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-120,122,123,127-129,135-137,143-145,194-243,366 and 367 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the amendment filed 3/4/04. Claims pending are 70-120, 122, 123, 127-129, 135-137, 143-145, 194-243, 366 and 367. Claims 70, 119, 122 and 242 have been amended. Claims 366 and 367 have been added.

Claim Rejections - 35 USC § 112

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The scope of enablement rejection of Claims 70 and 122 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of the record.
3. The scope of enablement rejection of Claims 119, 120, 242 and 243 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of the record.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The rejection of Claims 70-75, 77, 88, 90-94, 104-108, 110-115, 119, 120, 143 and 145 under 35 U.S.C. 102(b) as being anticipated by Stankov (WO 96/00576) is maintained for the reasons of the record.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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7. The rejection of Claims 78-87, 96-103, 109 and 116-118 under 35 U.S.C. 103(a) as being unpatentable over Stankov is maintained for the reasons of the record.

8. The rejection of Claims 76, 89, 122, 123, 127-129, 135-137, 144, 194-214 and 216-243 under 35 U.S.C. 103(a) as being unpatentable over Stankov in view of Horner et al. and Bent III et al. is maintained for the reasons of the record. New Claim 366 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stankov in view of Horner et al. and Bent III et al. as applied to Claim 128. New Claim 367 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stankov in view of Horner et al. and Bent III et al. as applied to Claim 136.

9. The rejection of Claims 95 and 215 under 35 U.S.C. 103(a) as being unpatentable over Stankov either alone or in view of Bent III et al. and Horner et al. and further in view of either McCaffrey et al. or Haria et al. is maintained for the reasons of the record.

Double Patenting

10. Applicant is advised that should claims 128 and 136 be found allowable, claims 366 and 367, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Response to Arguments

11. Applicant's arguments filed 3/4/04 have been fully considered but they are not persuasive.

In response to the Applicant's argument that "a person having ordinary skill in the art reading Applicant's specification would have been able to practice the presently claimed invention without undue experimentation", it is noted that the burden of enabling the curing and/or prevention of a disease would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such diseases and the difficulty of proof that the administration of the drug was the agent that acted to cure and/or prevent the condition. Thus, the examples in the specification are directed to the treatment of said conditions rather than the claimed elimination. The specification does not provide any working examples that would indicate the claimed antifungal agents are capable of completely eliminating asthma and AFS. Further, the prior art currently does not recognize the possibility of curing either condition by pharmacological therapy. With respect to the claimed preventing/prophylaxis of said conditions, the specification does not provide any working examples that would indicate the claimed antifungal agents are capable of preventing asthma and AFS. The Examples referred to in the Remarks (see p. 19) are not persuasive because there is no proof that the patient would have not exhibited symptoms of either asthma or rhinosinusitis had he not stopped taking the antifungals.

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With respect to the Stankov reference, the Applicant argues that the reference "does not disclose the successful treatment of both non-invasive fungus-induced rhinosinusitis and asthma." See p. 21 of the Remarks. In response, Stankov explicitly teaches treating patients having the symptoms of asthma, allergic rhinitis and blocked nose by daily oral administration of 1g of nystatin (or amphotericin) for 6 months. See col. 41, lines 5-17.

With respect to the 103(a) rejection of Claims 76, 89, 122, 123, 127-129, 135-137, 144, 194-214 and 216-243 over Stankov in view of Horner et al. and Bent III et al., the Applicant argues that Stankov never mentions sinusitis, let alone non-invasive fungus-induced rhinosinusitis. See pp. 23-24. In response, Stankov teaches treating patients having dust allergies. See col. 41, lines 6. Further, Stankov teaches "an almost complete disappearance" of the following symptoms: allergic rhinitis, asthma attacks and blocked nose, as a result of antifungal treatment. See col. 41, lines 10-11. Sinusitis is defined by Asthma Medical Glossary

(<http://asthmatrack.org/medsglossary.html#sinus>) as follows:

Inflammation of the sinus cavities. Its symptoms include headache (particularly upon waking,) nasal drainage (rhinorrhea,) jaw and/or teeth sensitivity, swelling around the eyes, nasal congestion and loss of smell. Causes can be infection (viral, bacterial or fungal,) medicines (their side-effects,) and allergies, specifically, when allergic or chronic rhinitis causes sinusitis. Allergies are the leading cause of chronic (long-term) sinusitis; structural abnormalities are also a contributor.

Therefore, "blocked nose" taught by Stankov reads on sinusitis. With respect to the etiology of the rhinitis and sinusitis, Horner et al. teach that fungal spores "are universal atmospheric components indoors and outdoors and are now generally recognized as

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important causes of respiratory allergies", including asthma and rhinitis. See p. 164.

Thus, it is reasonable to conclude that dust allergy symptoms taught by Stankov have fungal etiology. Further, the Applicant argues that the Bent and Kuhn reference ("Bent III et al.") fails to correct the deficiencies of Stankov because it teaches that topical irrigations are unsuccessful at treating AFS. See p. 24 of the Remarks. In response, Bent III et al. teach that only irrigations with **fluconazole** were ineffective, but either ketoconazole or amphotericin B were "the most effective" and would be "the best drugs" for topical antifungal treatment of AFS as a supplement to other surgical and medical therapy. See p. 1332, Results; p. 1334, Conclusion. Further, in response to the Applicant's arguments on p. 25 of the Remarks, it is noted that Table III of Bent III et al. shows that in vitro susceptibility of fungi to ketoconazole was higher than that to either amphotericin B or nystatin.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

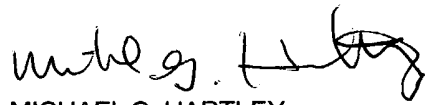
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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ml
6/28/04


MICHAEL G. HARTLEY
PRIMARY EXAMINER